

#### (12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

#### (19) World Intellectual Property Organization International Bureau



### 

## (43) International Publication Date 18 December 2003 (18.12.2003)

#### **PCT**

# (10) International Publication Number WO 03/103547 A1

(51) International Patent Classification7:

\_ \_ \_

- (21) International Application Number: PCT/NL03/00418
- (22) International Filing Date: 5 June 2003 (05.06.2003)
- ·

Dutch

A61F 5/01

(26) Publication Language:

English

(30) Priority Data:

(25) Filing Language:

1020777

6 June 2002 (06.06.2002) NL

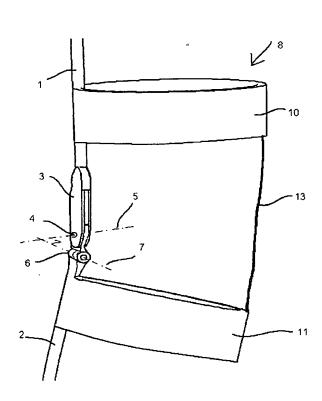
- (71) Applicant (for all designated States except US): KVLMT, B. V. [NL/NL]; Palatijn 13, NL-7521 PN Enschede (NL).
- (72) Inventors; and
- (75) Inventors/Applicants (for US only): BESSELINK, Mark, Stefan [NL/NL]; Goudsbloemstraat 44, NL-7531 DE Enschede (NL). VAN LEERDAM, Nicolaas, Gerardus, Adrianus [NL/NL]; Parijsstraat 19, NL-7559 KN

Hengelo (NL). VAN DER WOUDE, Jurrie [NL/NL]; Ter Wadding 8, NL-7608 LH Almelo (NL).

- (74) Agent: SCHUMANN, Bernard, Herman, Johan, Ir.; Schumann Patent Consultancy B.V., Boddenkampstraat 51, NL-7522 BZ Enschede (NL).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO,

[Continued on next page]

(54) Title: ORTHESIS WITH MULTIPLE HINGE



orthopaedic device (57) Abstract: An comprises: a structure comprising two substantially rigid parts, for instance a rod, which parts are coupled to each other by means of hinge means and each comprise fastening means for optional temporary fastening to a limb part, wherein a pivot axis of the hinge means extends at least more or less in the region and in the direction of the pivot axis zone of the relevant joint. The device according to the invention has the feature that the hinge means comprise two hinges, the respective pivot axes of which extend in directions which make an angle with each other of 90  $\pm$  40, preferably 90  $\pm$  20.

WO 03/103547 A1

#### WO 03/103547 A1

SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, — with amended claims GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

#### Published:

with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

#### ORTHESIS WITH MULTIPLE HINGE

The invention relates to an orthopaedic device, in particular a prosthesis or an orthosis, for the purpose of replacing respectively supporting the function of at least one part of a human limb with a pivotable joint, for 5 example a leg with a knee or an arm with an elbow, on either side of which joint there extend respective limb parts, such as a lower leg and an upper leg respectively a lower arm and an upper arm, which device comprises:

a structure comprising two substantially rigid parts, 10 for instance a rod, which parts are coupled to each other by means of hinge means and each comprise fastening means for optional temporary fastening to a limb part,

wherein a pivot axis of the hinge means extends at least more or less in the region and in the direction of 15 the pivot axis zone of the relevant joint.

Such a device is known from for instance US-A-5 792 086 and GB-A 2 099 309.

An orthosis is an assist means for supporting a limb with a reduced functionality and can be applied for 20 instance with a paralysed leg. An orthosis consists generally of at least two parts. First of all there are components which stabilize a body joint such as an elbow or an ankle in one or more directions. Such a hinge part generally has one fixed pivot axis.

25

A first problem of known orthoses is that the construction of an orthosis generally takes place on the basis of a positive plaster model of the shape of the limb in a resting and non-loaded position. Owing to load and to movement the shape of the limb changes, for instance the 30 angle between lower leg and upper leg in the frontal plane. It is the object to mimic the loaded position by manipulating the plaster model, whereafter the construction of the orthosis takes place on the basis of this thus manipulated plaster model. The results of such a

2

manipulation are however not readily predictable, which results in the orthosis having to be corrected afterward, which is difficult and labour-intensive. For this reason the correction is not carried out in some cases, which 5 results in a non-optimal orthosis for the user. A second problem of known orthoses is that a rotation is generally only possible about one fixed main rotation axis of the orthosis which generally corresponds with the characteristic rotation axis of the joint for stabilizing. 10 The characteristic rotation axis makes possible the characteristic movement of a limb, for instance flexing of a knee. In the case of a non-impeded bending of a limb however, the rotation axis of the relevant joint will generally also change direction. This known problem is 15 addressed in the above stated two publications. An orthosis with a fixed main rotation axis therefore obstructs the movement of the relevant joint and the associated limb parts. This obstruction results in undesirable stresses on the joint and the limb parts.

With a view to the above, the invention provides an orthopaedic device of the type stated in the preamble which has the feature that the hinge means comprise two hinges, the respective pivot axes of which extend in directions which make an angle with each other of 90  $\pm$  40 , 25 preferably 90 ± 20 . .

20

The pivot axes can intersect in the manner of a cardan joint. In a preferred embodiment however, the device according to the invention has the feature that the pivot axes are located spatially at a mutual distance, which 30 distance is chosen such that it corresponds with the pivoting characteristics of the relevant joint. The best possible match can hereby be realized with the pivoting characteristics of the relevant joint.

A preferred embodiment of the device according to the 35 invention is characterized by bounding means for limiting to a chosen angular position at least one of the pivoting movements of at least one of the hinges.

3

Owing to the stated measures the loaded position can be reached by relative rotation of the orthosis parts without manipulation of the plaster model as discussed above, while the definitive position can be determined 5 during use of the orthosis by adjusting the desired angle with the bounding means adapted for this purpose, whereby a result that is optimal for the user can be achieved in simple manner, without the later correction required in the known orthosis.

A second advantage of the measures according to the invention is that the rotation of the orthosis according to the invention corresponds better to the natural rotation of the joint in question, thereby removing a significant limitation in the movements of the relevant joint.

10

15

Specified for this purpose is a device according to the invention with bounding means for limiting the pivoting movement of a hinge to a chosen angular position. Such a device can advantageously have the feature according to the invention that the fastening means comprise at least two 20 divisible rings with adjustable periphery, one of which is connected to the one part and the other to the other part, and the bounding means comprise a flexible, tensively strong element, for instance a strap or cord, of optionally adjustable length, the ends of which are connected to these 25 rings such that the flexible element can bound the pivoting movement of at least one hinge.

It will be apparent that the flexible element has to positioned at a suitable location relative to the hinge in question, and must generally have an at least substantial 30 distance therefrom.

Alternatively, the device can have the feature that the bounding means comprise stop means added to a hinge.

The orthoses known from the two cited publications have a hinge part on either side of the relevant joint. 35 Such orthoses can be referred to as double-sided orthoses. According to the invention the device can advantageously have the feature that said structure is provided on only one side with hinge means. Better cosmetic results are

4

possible with such a device, which is found to be greatly valued by users during tests. Furthermore, with a single-sided orthosis the construction of the multiple hinge according to the invention can be simpler than in the case of a double-sided orthosis.

Two applications of the device according to the invention can be pointed to as important embodiments. In the one embodiment the device has the special feature that the device is a knee orthosis. In the other embodiment the device has the special feature that the device is a knee-ankle-foot orthosis.

The invention will now be elucidated on the basis of the annexed drawings of several random embodiments, to which the invention is not limited. In the drawings:

15 Fig. 1 shows a perspective view of a part of a knee orthosis according to the invention;

Fig. 2 is a front view of a knee orthosis in which the operation of the additional hinge is shown;

Fig. 3 is a view corresponding with Fig. 2 of the 20 orthosis arranged on a leg;

Fig. 4 is a front view of the single-sided orthosis according to Fig. 1, 2, 3 in the situation where the user is also standing on the relevant leg and the bounding means limit lateral displacement to the drawn value; and

Fig. 5 shows an alternative embodiment of a two-fold hinge.

Corresponding components are designated in all the figures with the same reference numerals.

Fig. 1 show an orthosis comprising an upper rod 1 and 30 a lower rod 2 which are coupled hingedly to each other by means of hinge means 3. Hinge means 3 comprise an upper hinge 4 with a pivot axis 5 and a lower hinge 6 with a pivot axis 7. The pivot axes 5 and 7 correspond respectively with the usual pivoting movement of the knee 35 and a swivelling movement substantially perpendicular thereto.

In order to fasten the orthosis 8 to the leg of a user, use is made of two sets of divisible rings with

5

adjustable periphery, which in accordance with Fig. 2, 3 and 4 are designated respectively 9, 10, 11, 12.

The rings 10 and 11 are connected to each other by means of a flexible, tensively strong element 13, for

5 instance a strap or cord of optionally adjustable length, such that this element 13 functions as limit to the swivelling movement of hinge 6 and allows the knee to move unhindered over the free swivel zone. Reference is also made in this respect to Fig. 4 in which the flexible

10 element in its tensioned position limits the lateral swivelling movement of said hinge 6. It is noted that it is not necessary in all conditions for the bounding element 13 to be situated diagonally on the other side of rings 10, 11 in relation to hinge 6.

The orthosis 9 can for instance be used to support a knee which may only be loaded in a determined position rotated in the frontal plane, for instance in the case of cartilage problems in the knee.

Fig. 2 and 3 show the knee orthosis 8 in bent position in accordance with the position of a leg wherein the lower leg makes an angle of for instance about 90 with the upper leg. Particular reference is made in this respect to Fig. 3. said swivelling of the lower leg takes place due to the operation of hinge 4 and a rotation about pivot axis 5. For 25 a lateral displacement of the lower leg, as shown in broken lines, a swivelling takes place about pivot axis 7 of hinge 6. In this manner it is possible to effectively follow the desired movements of the knee, and the functionality of the knee in question can be substantially supported. In Fig. 2 and 3 in the position drawn in broken lines the relevant components are provided with reference numerals with an accent.

Figure 5 shows hinge part 3 with the associated components on enlarged scale.

15

6

#### CLAIMS

1. Orthopaedic device, in particular a prosthesis or an orthosis, for the purpose of replacing respectively supporting the function of at least one part of a human limb with a pivotable joint, for example a leg with a knee or an arm with an elbow, on either side of which joint there extend respective limb parts, such as a lower leg and an upper leg respectively a lower arm and an upper arm, which device comprises:

a structure comprising two substantially rigid parts, for instance a rod, which parts are coupled to each other 10 by means of hinge means and each comprise fastening means for optional temporary fastening to a limb part,

wherein a pivot axis of the hinge means extends at least more or less in the region and in the direction of the pivot axis zone of the relevant joint,

characterized in that

وبري

the hinge means comprise two hinges, the respective pivot axes of which extend in directions which make an angle with each other of 90  $\,\pm\,$  40 , preferably 90  $\,\pm\,$  20 .

2. Device as claimed in claim 1.

20 characterized in that

the pivot axes are located spatially at a mutual distance, which distance is chosen such that it corresponds with the pivoting characteristics of the relevant joint.

3. Device as claimed in claim 1,

25 characterized by

bounding means for limiting to a chosen angular position at least one of the pivoting movements of at least one of the hinges.

4. Device as claimed in claim 3,

30 characterized in that

the fastening means comprise at least two divisible rings with adjustable periphery, one of which is connected

7

to the one part and the other to the other part, and the bounding means comprise a flexible, tensively strong element, for instance a strap or cord, of optionally adjustable length, the ends of which are connected to these rings such that the flexible element can bound the pivoting movement of at least one hinge.

- 5. Device as claimed in claim 4, characterized in that the bounding means comprise stop means added to a 10 hinge.
  - 6. Device as claimed in claim 1, characterized in that said structure is provided on only one side with hinge means.
- 7. Device as claimed in claim 1, characterized in that the device is a knee orthosis.

  8. Device as claimed in claim 1, characterized in that
- 20 the device is a knee-ankle-foot orthosis.

## AMENDED CLAIMS

# [Received by the International Bureau on 10 November 2003 (10.11.2003); original claims 1-8 replaced by amended claims 1-6 (2 pages)]

1. Orthopaedic device, in particular a prosthesis or an orthosis, for the purpose of replacing respectively supporting the function of at least one part of a human limb with a pivotable joint, for example a leg with a knee or an arm with an elbow, on either side of which joint there extend respective limb parts, such as a lower leg and an upper leg respectively a lower arm and an upper arm, which device comprises:

a structure comprising two substantially rigid parts, for instance a rod, which parts are coupled to each other by means of hinge means and each comprise fastening means for optional temporary fastening to a limb part,

wherein a pivot axis of the hinge means extends at least more or less in the region and in the direction of the pivot axis zone of the relevant joint,

15 characterized in that

the hinge means comprise two hinges, the respective pivot axes of which extend in directions which make an angle with each other of  $90^{\circ} \pm 40^{\circ}$ , preferably  $90^{\circ} \pm 20^{\circ}$ ;

in that bounding means are present for limiting to a 20 chosen angular position at least one of the pivoting movements of at least one of the hinges;

and in that

the fastening means comprise at least two divisible rings with adjustable periphery, one of which is connected to the one part and the other to the other part, and the bounding means comprise a flexible, tensively strong element, for instance a strap or cord, of optionally adjustable length, the ends of which are connected to these rings such that the flexible element can bound the pivoting movement of at least one hinge.

2. Device as claimed in claim 1, characterized in that

the pivot axes are located spatially at a mutual distance, which distance is chosen such that it corresponds with the pivoting characteristics of the relevant joint.

3. Device as claimed in claim 1,

characterized in that the bounding means comprise stop means added to a hinge.

the device is a knee-ankle-foot orthosis.

4. Device as claimed in claim 1, characterized in that said structure is provided on only one side with hinge means.

5. Device as claimed in claim 1, characterized in that the device is a knee orthosis.6. Device as claimed in claim 1, characterized in that

5

10

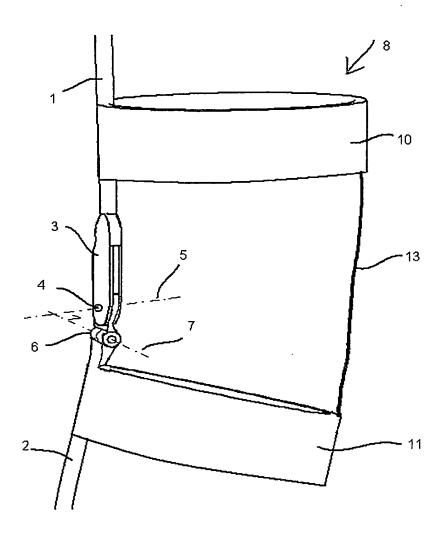


FIG. 1

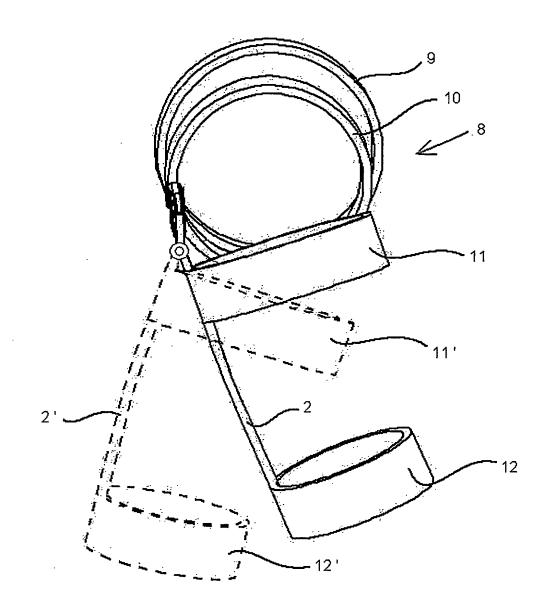
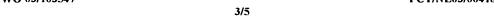


FIG. 2



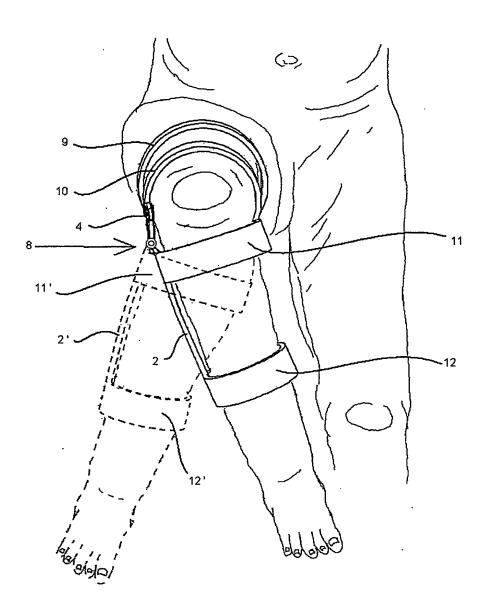


FIG. 3

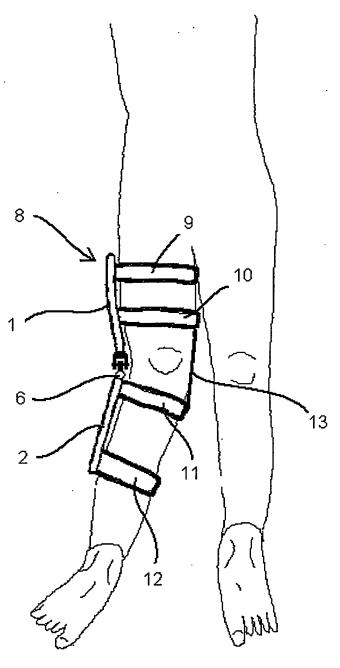
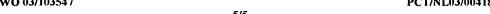


FIG. 4



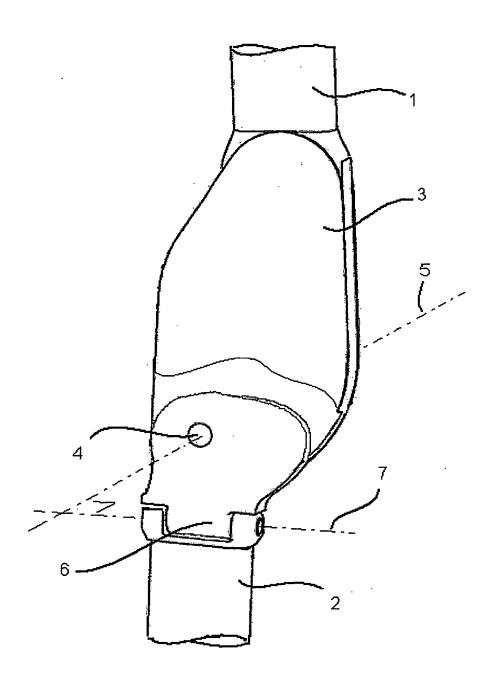


FIG. 5